Department of Veterans' Affairs
Harry S. Truman Memorial Veterans' Hospital
800 Hospital Drive
Columbia, MO 65201

HPM 589A4-321
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Issued by: Research

Human Research Protection Program

1. **PURPOSE**: To delineate policy and procedures relating to the Human Research Protection Program (HRPP) at the Harry S. Truman Memorial Veterans' Hospital (HSTMVH) and the affiliated Missouri Foundation for Medical Research (MFMR). This program will ensure the protection of human research subjects who participate in research programs at the HSTMVH.

2. **POLICY**: The activities related to human subject research will be carried out in accordance with all applicable federal laws and regulations including the Belmont Report.

3. **BACKGROUND:**

a. The HSTMVH will conduct the HRPP in conjunction with the University of Missouri-Columbia Health Sciences' Institutional Review Board (HS-IRB) through an approved Federal Wide Assurance #FWA00002426. A Memorandum of Understanding (MOU) delineating details of this arrangement is on file in the Research Office.

b. The HRPP will be conducted in accordance with Federal Law 38 CFR 16 & 17 (Common Law), VHA Handbook 1200.5 and other applicable Department of Health & Human Services (DHHS) and Food & Drug Administration (FDA) regulations.

4. **RESPONSIBILITIES:**

a. The Hospital Director of the HSTMVH will be the signatory official for the FWA of the institution and will maintain ultimate responsibility for the oversight of the HRPP.

b. The Associate Chief of Staff for Research and Development (ACOS/R&D) will maintain overall responsibility for the entire research program including the implementation of the HRPP.

c. The VA Research and Development (R&D) Committee will review and approve all research conducted at the HSTMVH. The R&D Committee will provide oversight of HS-IRB activities to assure compliance with applicable regulations. Specific responsibilities of VA R&D will include the following:

(1) To ensure the scientific quality and appropriateness of all research involving human subjects;

(2) To annually evaluate all research studies involving human subjects to assure regulatory compliance and protection of human subjects;

(3) To review the membership and performance of the HS-IRB to ensure compliance with all applicable regulations.

d. Veterans' Affairs (VA) Principal Investigators (PI's) will be responsible for the following:

(1) Adhering to the policies and requirements of the HS-IRB and the VA Research Service, including VHA Handbook 1200.5 paragraph 10; specifically, PIs are required to comply with HS IRB policies regarding adverse event reporting, continuing review reports, filing amendments, informed consent, recruitment of subjects, vulnerable populations, protocol approval, and other policies as may be applicable for specific projects.

(2) Securing signatures from human research participants or participants' legally authorized representative on all HS-IRB approved informed consent documentation and the legally effective authorization for the use and disclosure of the subject's protected health information (PHI);

(3) Implementing human research studies to include the following:

(a) Protocol design and methods that minimize risks to subjects while maximizing research benefits;

(b) Ensuring that all members of the research team involved in human research have successfully completed the VA Central Office required training for human subject protection, Good Clinical Practice (GCP), VHA privacy and Health Insurance Portability and Accountability Act (HIPAA) provided by the VA (see Appendix A for training sites);

(c) Ensuring that all members of the research team comply with the directives of the HS-IRB and the VA R&D Committee;

(d) Ensuring that the informed consent documentation, processes, and compliance standards are met;

(e) Ensuring that all study personnel receive annual training to assume responsibility for the proper conduct of the research study;

(f) Notifying the HS-IRB, VA R&D Committee, study participants, and the study sponsor of any problems, including side effects, encountered when conducting human research, as well as the timely submission of all required reporting and documentation (e.g. adverse events, data and safety monitoring board reports, and continuing review);

(g) Obtaining the HS-IRB and the VA R&D Committee review and approval prior to initiating a research project by completing the following steps:

1. Completing and submitting the appropriate HS-IRB application (e.g., exempt, expedited, full board) to request the HS-IRB review the plan for research and all supporting documentation to include the full research protocol, risk/benefit analysis, recruiting plan and any recruitment materials, data collection tools, surveys and/or questionnaires, and

2. Submitting to the VA Research Office the "Request to Conduct Research" application (human and/or animal, as applicable); Conflict of Interest forms; and other information as requested;

(h) Following study approval, completion of the HS-IRB Continuation Review Report annually to update the HS-IRB and VA R&D Committee regarding study progress;

(i) Informing the HS-IRB of any financial conflicts of interests pursuant to the Conflict of Interest (COI) policies as stated in the Business Policy and Procedure Manual, VHA Directive 1200 and the VHA Handbook 1200.13;

(j) Documentation of research participation in study participants' VA Computerized Patient Record System (CPRS) and/or paper medical record, including consent and privacy documentation, investigation drug alerts, and completion or termination of study participation.

e. The Human Research Compliance Officer will be responsible for the following:

(1) Evaluating the institution's adherence to applicable federal and state regulations and accreditation standards governing human subject research;

(2) Evaluating the functions of the affiliated HS-IRB as they relate to VA policies;

(3) Evaluating the investigator's compliance of human research protections and adherence to applicable regulations and procedures;

(4) Evaluating the institution's quality improvement and quality assurance programs to establish systematic monitoring procedures for the human subject research programs;

(5) Communicating between the HS-IRB and the VA R&D Committee.

5. **DEFINITIONS**:

a. Health Sciences Institutional Review Board (HS-IRB): The approval body for human research located at the University of Missouri-Columbia.

b. Principal Investigator (PI): The individual who will be accountable for the proposal and the execution of the research protocol, as designed, by overseeing the performance of research staff to ensure the completion of all research activities.

c. Research and Development (R&D) Committee: The organization that will provide oversight of the HS-IRB, Subcommittee for Research Safety (SRS) and Subcommittee for Animal Studies (SAS) to assure compliance with applicable regulations.

d. Belmont Report: The summary of the basic ethical principles identified by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This report puts forth a statement of basic ethical principles and guidelines to assist in resolving the ethical problems confronted when conducting research with human subjects.

e. Good Clinical Practices (GCP): The international ethical and scientific quality standard for designing, conducting, monitoring, recording, auditing, analyzing and reporting studies. Adhering to the GCP will ensure that the research data reported will be collected

using credible and accurate methods to protect research participants' rights and confidentiality.

f. Food and Drug Administration (FDA): The federal agency that promotes public health by promptly and efficiently reviewing clinical research and taking appropriate actions with regard to marketing of the regulated process.

g. Health Insurance Portability and Accountability Act (HIPAA): The regulation that includes under Title II an Administrative Simplification Compliance Act that applies to the following four areas:

(1) Patient privacy;

(2) Security of protected patient information;

(3) Standardization of transactions and code sets;

(4) Standard Identifiers for such entities as employers and healthcare providers.

h. Office for Human Research Protection (OHRP): The Federal government office that issues assurances and oversees compliance with regulations concerning human research.

i. Office of Research Oversight (ORO): The Veteran Health Administration (VHA) office that will advise the Under Secretary for Health on matters related to the protection of human research subjects, animal welfare, research safety, and research misconduct. ORO supports and promotes the responsible conduct of research through periodic inspections and evaluations of research integrity, and through investigations of allegations of non-compliance with policies and regulations at VA research facilities.

6. **PROCEDURES**:

a. All investigators, research coordinators and other research personnel that have access to personally identifiable information will be required to meet the educational requirements of the human subject's protection and the VA Good Clinical Practice web-based training, if applicable. Education will be updated on a bi-annual basis.

b. The HRPP annual budget will be submitted as part of the overall research budget for the Research Service by the ACOS/R&D. The systematic budgeting process for the HRPP includes consideration of the following factors:

(1) Analysis of the volume of research to be reviewed;

(2) Feedback from HS-IRB and VA members and staff;

(3) Resources review will include but not be limited to: personnel, materials/supplies, space, capital equipment and training/education.

c. HRPP support will be provided by the HSTMVH and the MFMR. Industry-sponsored studies involving human subjects will have an established fee imposed to support the HRPP. The R&D Committee shall not approve industry-sponsored studies with human subjects that

will be administered by an entity that has not signed a written acknowledgment and agreement to pay such fee.

d. All "Requests to Conduct Research" applications must be submitted to the VA Research Office for administrative review prior to review by the VA R&D committee.

e. Submission of applications for HS-IRB approval must be submitted electronically at https://irb.missouri.edu/eirb and in hardcopy to IRB, DC074.00, 125 Folk.

f. Requests for continuing research reviews, amendments, adverse event reports, and consent forms will be reviewed and approved by the HS-IRB.

g. The VA Research Service will continuously monitor and address any questions, concerns or complaints regarding human research by use of a formal complaint system maintained within the VA Research Service.

7. **REFERENCES**: VHA Handbook 1200.5

8. **RESCISSION**: HPM 589A4-321, April 27, 2004

9. **RESPONSIBILITY**: Research Service (RESEARCH)

APPROVED:

GARY L. CAMPBELL
Director

Appendix A
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VHA Privacy Policy Training is available on the Veterans Health Administration (VHA) Privacy Policy Training Web Site (http://www.vhaprivacytraining.net/main.htm). This site will allow you to register and take the mandatory training course detailing the VHA Privacy Policy. The basic course is designed to be finished in 50-60 minutes. If you choose to read information behind the MORE buttons, self-test questions, and scenarios, it may take you about 30 more minutes to finish.

All VHA staff are required to complete the training annually. All new employees are required to take this training within 30 days of being hired. A team of subject matter experts from the VHA Privacy Office and VA Employee Education System (EES) created this training.

To review VHA Privacy Policy, please read the "VHA Handbook 16-5.1 Privacy and Release of Information". Please note reading this document does not satisfy the course completion requirements.